COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.11.2009
C(2009)9015

COMMISSION DECISION

of 11.11.2009

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(ONLY THE FRENCH, DUTCH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to Regulation EC (No) 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[3], and in particular Articles 28(3) and 45(3) thereof,

Having regard to the applications submitted by Schering Plough Europe on 27 July 2008 and on 21 September 2008 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinions of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 24 September 2009 and on 12 October 2009,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b", which

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 159, 27.6.2003, p. 24.
3 OJ L 378, 27.12.2006, p. 1.

is entered in the Community Register of Medicinal Products under number(s) EU/1/00/131/001-050 and the placing on the market of which was authorised by Decision C(2000)1407 of 25 May 2000, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2000)1407 accordingly.

(3) By Decision P/64/2008, the European Medicines Agency agreed to the paediatric investigation plan for "PegIntron - Peginterferon alfa-2b".

(4) It has been verified that the application(s) complies (comply) with all measures contained in the agreed completed paediatric investigation plan, and that the Summary of Product Characteristics reflects the results of the studies conducted in compliance with this agreed paediatric investigation plan.

(5) It is therefore appropriate to include a statement indicating compliance of the application with the agreed completed paediatric investigation plan in the marketing authorisation.

(6) For the purpose of the application of the Article 45(3) of Regulation EC (No) 1901/2006, it has been verified that significant studies contained in the agreed paediatric investigation plan have been completed after the entry into force of that Regulation.

(7) It is therefore appropriate to indicate a statement in that regard in the marketing authorisation.

(8) The marketing authorisation should be updated, and Decision C(2000)1407 amended accordingly.

(9) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2000)1407 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1) The following Statement of Compliance referred to in Article 28(3) of Regulation (EC) No 1901/2006 is added:

[4] OJ L 311, 28.11.2001, p. 67.

The development of this product has complied with all measures in the agreed paediatric investigation plan (Decision P/64/2008). For the purpose of the application of the Article 45(3) of Regulation EC (No) 1901/2006, significant studies in the agreed paediatric investigation plan (Decision P/64/2008) were completed after the entry into force of that Regulation.

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België.

Done at Brussels, 11.11.2009

For the Commission
Heinz ZOUREK
Director-General